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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/809,173	03/16/2001	Bernard Charles Sherman	PT-1896000	3792

23607 7590 03/21/2002

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/809,173

Applicant(s)

SHERMAN, BERNARD CHARLES

Examiner

Humera N Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2001.
- 2a) ☐ This action is **FINAL**. ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the IDS filed 04/05/01, the Priority papers filed 04/05/01, the Preliminary Amendment filed 05/30/01 and the CFR filed 05/30/01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5, 7, 8, 12, 13 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "most" in claim 1 is a relative term, which renders the claim indefinite. The term "most" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term is indefinite because it is unclear as to whether the process requires a conversion of more than 50%.

Claims 5, 7 and 8 recite the limitation "other" on pages 13 and 14. There is insufficient antecedent basis for this limitation in the claims. The term "other" is indefinite because it does not refer to any previous excipients used in the process.

The term "substantially" in claims 12, 13 and 18 is a relative term, which renders the claim indefinite. The term "substantially" is indefinite because it does not state with clarity the exact percentage required for the conversion.

The term "about " in claims 12 and 18 is a relative term, which renders the claims indefinite. The term "about" is indefinite because it does not demonstrate a specified percentage amount.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harris *et al.* (US Pat. No. 4,743,450) alone or in view of Hoefle *et al.* (US Pat. No. 4,344,949).

Harris *et al.* teach the use and process of making a solid pharmaceutical composition in the form of tablets, capsules and sachets using wet granulation and comprising a method of stabilizing ACE inhibitor drugs (quinapril) in combination with an alkaline agent (magnesium carbonate) as the stabilizer, acid addition salts (hydrochloride), a solvent (water) and various excipients (see entire document). Harris *et al.* are deficient in the sense that they do not expressly suggest the use of moexipril

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in their formulation. Harris et al. list only a selective group of ACE inhibitors (enalapril, quinapril, indolapril) for incorporation into the formulation and require at least one ACE inhibitor. It would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the various ACE inhibitors available, including moexipril, in combination with alkaline agents with the expectation of obtaining a suitable solid preparation with beneficial effects in lowering blood pressure and enhanced storage stability. Such skill is also evident from the reference of Hoefle et al.

Hoefle et al. teach the use of a tableted pharmaceutical composition and method for treating hypertension comprising moexipril, quinapril, their acid addition salts, alkaline agents and excipients (see entire document). In addition, according to the specification, on page 1, lines 24-25, Applicant recognize the use of quinapril and moexipril and their acid addition salts disclosed in US Pat. No. 4,344,949. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any ACE inhibitor, particularly moexipril, in combination with alkalizing agents, to obtain a highly stable and effective drug composition for use in the treatment of hypertension.

Regarding the percentages, there is no criticality seen and it is deemed obvious that one of ordinary skill in the art would determine suitable percentage ratios through manipulative and routine experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:00P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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